Remarks

I. Status of the Application and Claims

As originally filed, the present application had a total of 19 claims. All of these except for 1-7, 9 and 17 were withdrawn as the result of a restriction requirement. Applicants have now canceled these claims and introduced new claims 20-45.

II. The Amendments

The specification was amended to add a section heading and to cross reference related applications relied upon for priority.

New claims 20-45 have been introduced herein. Support for these claims may be found as set forth in Table 1.

Table 1: Support for New Claims

New Claim	Support
claims 20 and 22	original claim 1; Examples 3 and 4
claim 21	page 1 of the Sequence Listing (Note nucleotides 252-1673 are identified as the coding sequence); see also original claim 1 and page 21, lines 18-21
claims 23-26	page 5 of the specification, lines 7-13
claim 27	original claims 1 and 4
claims 28-31	page 4 of the specification, line 31- page 5, line 3
claim 32	page 12 of the specification, lines 5-18; Example 3, page 21, line 22 – page 22, line 3
claims 33 and 34	page 12, lines 18-29; Example 4, page 23, line 4 – page 24, line 2
claims 35 and 36	original claim 9

claim 37	original claim 8
claim 38	page 12, line 1 – page 13, line 16
claim 39	page 4, lines 1-9
claims 40-43	page 9, line 18 – page 10, line 2
claims 44 and 45	page 4, lines 10-26

None of the amendments made to the specification or claims adds new matter to the application. The entry of these amendments is therefore respectfully requested.

III. Request for Inclusion of Method Claims

Although the Examiner has removed claims to methods for producing amino acids as the result of a restriction requirement, Applicants respectfully request reconsideration. The patentability of such claims clearly depends upon the bacteria and vectors used in the procedure. In other words, Applicants are not claiming fermentation as a means of producing amino acids per se. Therefore, if the claims in the application directed to vectors and bacteria are patentable, then claims to methods of making amino acids using the bacteria should also be patentable. A first use for a composition is almost always included as part of a restriction group.

The Rejections

I. Rejection of Claims Under 35 U.S.C. §101

On pages 2 and 3 of the Office Action, the Examiner rejects all pending claims based upon the allegation that Applicants' claimed invention lacks any credible utility. The Examiner acknowledges that the claimed polynucleotides encode a transcription regulator but argues that, since this has not been linked to a specific disease, its only function would be for future research.

Applicants respectfully traverse this rejection.

The present application demonstrates that the claimed polynucleotides can be used in procedures leading to an enhancement of amino acid production by bacteria. Specifically, the identification of the sequence of the bacterial mikE17 gene makes it possible to design vectors for destroying the activity of its endogenous counterpart (see Example 3) and to integrate such vectors into the chromosome of a bacterial host (see Example 4). As is demonstrated in Example 5, these procedures result in enhanced lysine production (see Table on page 26). Thus, the claimed polynucleotides may serve as a source for sequence elements used in the making of vectors for disrupting endogenous bacterial mikE17 which, in turn, leads to better fermentation productivity.

In light of the above considerations, Applicants submit that a practical, real world, utility has been identified for the polynucleotides claimed by Applicants. It is therefore respectfully requested that the rejection of claims under 35 U.S.C. §101 be withdrawn.

II. Rejections of Claims Under 35 U.S.C. §112, First Paragraph

On pages 3-5 of the Office Action, claims are rejected under 35 U.S.C. §112, first paragraph. The allegations made by the Examiner are set forth in items 6, 7 and 8. Below, Applicants respond to each allegation.

A. Response to Allegations in Item 6

In item 6, the Examiner rejects claims based upon the allegation that one of skill in the art would not be able to use the claimed invention because a credible utility has not been set forth in the application. The Examiner also argues that it would require undue experimentation for one of skill in the art to identify and screen all of the compounds falling within the scope of the claims.

Applicants respectfully traverse this rejection.

Applicants submit that the Examiner is using an inappropriate standard in assessing enablement. Enablement is judged from the viewpoint of each individual embodiment of a claim and is concerned with whether one of skill in the art can make and use every such

embodiment. It is not concerned with whether one of skill in the art can identify all of the embodiments falling within the scope of a claim.

Applicants submit that it would not take undue experimentation to synthesize any polynucleotide within the scope of the present claims or to carry out the molecular biology of cloning, transfection and selection needed to use the polynucleotide to improve bacterial amino acid production. The Examiner alleges that this would be impossible in the present case because a utility has not been identified. However, as discussed above, the application demonstrates that the claimed polynucleotides can be used to improve the production of amino acids by bacteria and this is a utility that should be sufficient to fulfill the requirements of patentability.

With respect to the question of whether one of skill in the art could determine whether a particular polynucleotide falls within the scope of a claim (a §112, second paragraph issue). Applicants submit that the comparison of polynucleotides to determine their sequence identity is a trivial matter for an ordinary molecular biologist. In addition, as far as Applicants know, all of the embodiments falling within the scope of the present claims have at least some utility in gene disruption procedures or in generating probes that can be used in conjunction with these procedures. If an issue in this regard arose, the experiments needed to settle the question are clearly described in Examples 2-5 of the application. For example, screening for the disruption of an endogenous mikE17 gene could be carried out as described or amino acid production of a transformants could be examined directly.

In light of the above considerations, Applicants submit that the present claims are fully enabled. It is therefore respectfully requested that the present rejection of claims based upon the enablement requirement be withdrawn.

B. Response to Allegations in Item 7

In item 7, the Examiner rejects claim 9 based upon the allegation that, in order to fulfill the deposit requirements of patent law, certain statements are needed with respect to deposited strain number 14143.

In response, Applicants undersigned attorney hereby states that the deposit of strain number 14143 was made under the terms of the Budapest Treaty. Upon the issuance of a patent, the strain will be irrevocably, and without restriction or condition, released to the public. Applicants believe that these statements should be sufficient to overcome the Examiner's rejections.

C. Response to Allegations in the Item 8

In item 8, claims are rejected based upon the written description requirement of patentability. It is alleged that claims encompass all polynucleotides encoding proteins having amino acid sequences 70% identical to that of SEQ ID NO:2 but the specification only shows one particular sequence. Thus, the Examiner argues that one of skill in the art would not conclude that Applicants were in possession of all of the polynucleotides falling within the scope of their claims.

Applicants respectfully traverse this rejection.

As discussed previously, the claimed polynucleotides do have a utility in providing DNA segments useful for gene disruption and, ultimately, for the production of bacteria with improved amino acid synthesis characteristics. It is true that the specification may only expressly recite the sequence for *C. glutamicum* mikE17. However, given the amino acid sequence of the mikE17 protein, it should be possible for one of skill in the art to identify every other protein with 70% sequence identity and, in principle, to make all of the polynucleotides encoding the sequences.

Although the claims encompass a very large number of compounds and structures, this does not mean that the written description requirement has not been met. Chemical claims often encompass many millions of compounds and are, nevertheless, valid. It should especially be noted that the present claims are *not* open-ended and, given enough time, one of skill in the art could write down every sequence within their scope. The fact that this is impractical, does not justify a conclusion that Applicants are not in possession of the claimed

invention. Patent law does not require physical possession of every embodiment of a claim for the written description requirement to be fulfilled.

III. Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

On pages 5 and 6 of the Office Action, the Examiner rejects claims under 35 U.S.C. §112, second paragraph. There are several distinct bases upon which the rejection is founded. Applicants respond to each below.

A. Claim 1 is rejected based upon the allegation that the phrase "polynucleotide sequence which codes for the mikE17 gene" renders the claim indefinite because the specific function of the gene product is not known. Since this phrase is no longer present in the claims as amended herein, Applicants submit that the Examiner's rejection has been obviated.

B. Claim 1 is also rejected based upon the allegation that the phrase "70% identical to a polynucleotide coding for a polypeptide that contains the amino acid sequence of SEQ ID NO:2" is indefinite because the specific nucleotide sequence/structure is not known or recited in the claim. In response, Applicants submit that the fact that a sequence is not expressly recited does not mean that it is not known. Chemical claims often have compounds presented as a core with many different variables groups. Even though each specific compound falling within the scope of the claims is not recited, it is well established that claims of this nature are valid. The present claims are no different. The amino acid structure of the protein is allowed to vary as long as 70% identity is maintained with SEQ ID NO:2. Similarly, the polynucleotide structure is allowed to vary with the limitation that it must always encode a protein falling within the scope of the claims. Therefore, one of ordinary skill in the art should be able to readily determine whether any given polynucleotide sequence is encompassed by the claims and they therefore meet the requirements of 35 U.S.C. §112, second paragraph.

C. The Examiner rejects claim 1 based upon the allegation that the phrase "preferably having the activity of the transcription regulator mikE17" renders the claim

indefinite. Since this phrase has been eliminated from the amended claims presented herein, Applicants submit that the Examiner's rejection has been obviated.

D. Claim 2 is rejected based upon the allegation that it is rendered indefinite due to the phrase "preferably recombinant DNA which is capable of replication in coryneform bacteria." The phrase objected to by the Examiner is no longer present in the amended claims. It is therefore submitted that this rejection has been obviated.

E. Claim 5 is rejected due to three phrases: "within the range of the degeneration of the genetic code;" "which hybridizes with the sequence;" and "sense mutations of neutral function." The last of these phrases has been eliminated from the claims introduced herein. Although no claims now recite "the degeneration of the genetic code," claim 21 refers to "degenerate variants." Applicants submit that this term may be found in textbooks on molecular biology and has an accepted meaning that would be understood by one of ordinary skill in the art. Finally, any claims defining polynucleotides based upon hybridization behavior now expressly indicate conditions under which hybridizations are performed. Applicants therefore submit that the Examiner's rejection has been overcome.

IV. Rejection of Claims Under 35 U.S.C. §102

On page 6 of the Office Action, the Examiner rejects claims 1 and 5 based upon the allegation that they are not novel. Claim 1 is rejected as being anticipated by Mahairas, *et al.* (Accession No. AQ757887). The Examiner alleges that the reference anticipates the portion of the claim directed to polynucleotides having 15 consecutive bases found within the amino acid sequence of SEQ ID NO:2. Since the claims introduced herein no longer include a provision for all polynucleotides with 15 consecutive bases of specified sequence, Applicants submit that the basis for rejection presented by the Examiner no longer exists.

Claim 5 is rejected based upon the allegation that it is anticipated by Lee, *et al.* (Accession No. BE636602). The Examiner alleges that the reference discloses a polynucleotide that will hybridize to SEQ ID NO:1 under low stringency conditions. In response, Applicants submit that the claims as amended herein either no longer define

polynucleotides based upon their hybridization characteristics or require conditions of high stringency. Thus, the Examiner's basis for alleging that the Lee reference is anticipatory no longer exists.

In light of the above considerations, Applicants submit that the references cited by the Examiner are not anticipatory and respectfully request that the rejection of claims under 35 U.S.C. §102 be withdrawn.

Conclusion

In light of the amendments and discussion above, Applicants submit that all of the Examiner's rejections have been overcome. It is therefore respectfully requested that these rejections be withdrawn and that the claims presently pending in the application be allowed.

If, in the opinion of the Examiner, a phone call may help to expedite the prosecution of this application, the Examiner is invited to call Applicants' undersigned attorney at (703) 905-2173.

Respectfully submitted,

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